

Remarks

Claim 3 and new Claim 16 are currently pending.

New claim rejection: Claim 3 has been rejected based on 35 USC § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The 6/15/2005 Office Action states:

Claim 3 lacks clarity, which renders the claim indefinite because the claim is directed to a method of determining a useful salt, but does not set forth in the claim what the salt is useful for. The terms "composition of matter" and "medicinal compound" are noted, but do not clarify the claimed invention since a composition has not been identified as being the claimed invention. Claim 3 also has not been established as a process for preparing a particular composition or as a method of treating a particular condition wherein the composition is administered to an individual.

Claim 3 is further indefinite because the claim describes steps that involve accomplishing a task, but does not clearly describes [sic] the task that is achieved. The claim recites a "medicinal compound" and "therapeutic efficacy", but does not specify the medicinal compound or what condition is being treated.

Continuing rejection: Claim 3 was also rejected under 35 USC § 102(a) as being anticipated by Chiese et al (US Patent No. 5,773,029) for the reasons disclosed on pages 3-5 of the Office Action mailed November 20, 2003.

Amendments:

Support for new Claim 16 can be found on at least page 17, lines 9-16. Claim 16 is Claim 2 reinstated.

Arguments

35 USC § 112, second paragraph

Applicant traverses the rejection of Claim 3 based on 35 U.S.C. 112, second paragraph.

Applicant objects to said rejection being raised at this point in the prosecution. Claim 3 is as originally presented as filed on 05/02/1997. MPEP 707.07(g) states that piecemeal examination is not to occur. Raising these rejections at this late stage of prosecution amounts to piecemeal prosecution.

Furthermore, the claim as originally presented is not indefinite as written, especially when read in light of the disclosure of the pending application:

A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants can be their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as **>any** special meaning assigned to a term is clearly set forth in the specification. See MPEP 2111.01.< Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the court in *In re Swinehardt*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought. [MPEP 2173.01]

The MPEP 2173.02 states:

The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. . . .

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
 - (B) The teachings of the prior art; and
 - (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.
- [Emphasis in original.]

The Office Action states that Claim 3 is indefinite because the claim does not set forth the usefulness of the salt. First, “The examiner’s focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available.” MPEP 2173.02. It is Applicant’s position that requiring the presence of the utility in the claim is not a reason for a 112, second paragraph rejection. Second, the usefulness of the salt is stated within the claim: “for use in making a composition of matter comprising an inclusion complex of said salt in a cyclodextrin”. Last, Claim 3 is definite, especially when read in light of the disclosure of the pending application. Please see discussions on at least the following pages: page 2, line 29 spanning to page 3, line 5; page 4, lines 30-31; page 5, lines 1-14; page 5, line 22 spanning to page 6, line 3; page 6, line 7 spanning to page 7, line 10 and page 8, line 24 spanning to page 9, line 32. Applicant respectfully requests that this rejection be reconsidered and withdrawn.

The Office Action states that Claim 3 is indefinite because the terms “composition of matter” and “medicinal compound” do not clarify the claimed invention since a composition has not been identified as being the claimed invention. Claim 3 is definite, especially when read in light of the disclosure of the pending application. Please see discussions on at least the following pages: page 3, lines 3-5, 14-31; page 5, line 22 spanning to page 6, line 3; and page 6, line 32 spanning to page 7, line 10. Applicant respectfully requests that this rejection be reconsidered and withdrawn.

The Office Action states that Claim 3 has not been established as a process for preparing a particular composition or as a method of treating a particular condition wherein the composition is administered to an individual. Claim 3 is a method of determining a useful salt for making a composition of matter comprising an inclusion complex of said salt in a cyclodextrin. The claim has been misunderstood. Applicant respectfully requests that this rejection be reconsidered and withdrawn.

The Office Action states that Claim 3 is indefinite because it does not clearly describe the task that is achieved. Claim 3 is definite, especially when read in light of the disclosure of the pending application. The invention is not limited to any particular medicinal compound or class of compounds. The invention concerns selecting, choosing, or locating

one or more salts of a compound. The claim has been misunderstood. Please see discussions on at least the following pages: page 2, line 29 spanning to page 3, line 5 and page 5, lines 6-11. Applicant respectfully requests that this rejection be reconsidered and withdrawn.

Rejection based on 35 USC § 102(a)

Claim 3 has been continually rejected under 35 USC § 102(a) as being anticipated by Chiese et al (US Patent No. 5,773,029). Responses thus far have not been found sufficient to overcome this rejection. The 11/20/2003 Office Action has been referenced as providing the basis of the rejection, different sections of Chiese, '029 are presented on pages 3-5, concluding with the statement: "The method described in the Cheisi, '029 for preparing multicomponent inclusion complexes anticipate the method of locating one or more salts of a compound and a method of determining a useful salt from within a series of salts as instantly claimed." Applicant traversed. In the 06/15/2005 Office Action, it is stated that Applicant argued that at least steps (a), (b), (c) and (f) of the instantly claimed method was not found in the Cheisi, '029 and said arguments were found to be unpersuasive, stating: "The Cheisi, '029 does set forth information, which expressly or inherently anticipate the instantly claimed invention."

Applicant traverses the 102(a) rejection. Regarding anticipation, the MPEP provides, in pertinent part:

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegall Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1063 (Fed. Cir. 1987). "When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art." *Brown v. 3M*, 265 F.3d 1349, 1351 60 USPQ2d 1375, 1376 (Fed. Cir. 2001) (claim to a system for setting a computer clock to an offset time to address the Year 2000 (Y2K) problem, applicable to records with year date data in "at least one of two-digit, three-digit, or four-digit" representations, was held anticipated by a system that offsets year dates in only two-digit formats). See also MPEP2131.02 "The identical invention must be shown in as complete detail as is contained in the claim." *Richland v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1931, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but is not an *ipsisimilis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). Note that, in some circumstances, it is permissible to

use multiple to use multiple references in a 35 U.S.C. 102 rejection. See MPEP § 2131.01. [MPEP 2131.]

.... The anticipating reference must contain within its four corners a sufficient description to enable one to practice the invention without experimentation or inventive skill. *Phillips Elec. & Pharmaceutical Indus. Corp. v. Thermal & Elec. Indus., Inc.*, 450 F.2d 1164, 1169, 171 USPQ 641, 644-45 (2d Cir. 1971); *Dewey & Almy Chem. Co. v. Mimex Co.*, 124 F.2d 986, 990, 52 USPQ 138, 142-43 (2d Cir. 1942); I Chisum, Patents § 3.04[1][6] (1985). See *CBS v. Sylvania Electric Prod., Inc.*, 415 F.2d 719, 725, 162 USPQ 577, 581 (1st Cir. 1969) (test is whether the prior art reference "describes the invention with sufficient clarity and specificity so that one skilled in the art may practice the invention without assistance from the patent claimed to have been anticipated.") [*Schering Corp. v. Precision-Cosmet Co., Inc.*, 614 F Supp 1368, 227 USPQ 278, 281 (D Del, 1985).]

Applicant describes and enables something that is not taught by Cheisi, '029:

This invention is based, *inter alia*, on the discovery that for a particular cyclodextrin, the solubility of a particular compound in an aqueous solution of a cyclodextrin is not independent of the salt employed. That is, different salts of the same compound can often exhibit widely differing solubilities in the same cyclodextrin. The phenomenon of differential solubility exhibited by different salts of a compound in the same cyclodextrin has not heretofore been known in the art. It has also been determined that the rank order of solubility, that is the increasing or decreasing order of solubility a series of salts in an aqueous cyclodextrin solution does not necessarily correlate with the order of salt solubility in water.

The discovery of such differential solubility of different salts in a particular cyclodextrin is surprising and unexpected based on conventional wisdom which teaches that the total solubility of an ionizable compound in a cyclodextrin-containing aqueous solution is the sum total of the solubility of all the species of the compound that exists in various forms in the solution.

....
Thus, based on conventional belief there is no reason to expect that different salts of a particular compound would be differentially solubilized in the same cyclodextrin since it is believed that the counter ion does not play a role in the complexation process.

Furthermore, the phenomenon of differential solubility is important because it makes possible the capability for increasing the loading of a particular compound in a cyclodextrin by testing a series of different salts of that compound and selecting a salt which affords a desired high solubility, thereby permitting the use of a lower amount of cyclodextrin relative to a less cyclodextrin-soluble salt. . . . [Page 5, line 22 spanning to page 6, line 2 and page 6, line 21 spanning to page 7, line 3, pending application.]

Applicant's discovery is used to identify which salt within a series of salts for a medicinal compound is best to use to complex the medicinal compound as the useful salt with a cyclodextrin to obtain the desired target solubility and, separately, to select the useful salt to permit making a total dose equal to or less than said maximum total dose. See pending application page 3, lines 6-13; page 3, line 30 spanning to page 4, line 12. To this end, a pharmaceutical salt of the medicinal compound is made, purchased, or otherwise obtained, with more than one pharmaceutically acceptable salt being obtained. The medicinal compound as the pharmaceutical salt, is added to a cyclodextrin solution to identify solubility of each salt individually. See pending application page 8, line 24 spanning to page 9, line 14; page 11, lines 5-17; page 11, line 30, spanning to page 12, line 6; page 13 (Table 1), and page 15, line 22 to page 16, line 5. From this set of steps, one is then able to identify the useful salt to use to form an inclusion complex with a specific cyclodextrin.

First, Cheisi, '029 concerns preparing a multicomponent inclusion complex comprising suspending the desired acidic drug, cyclodextrin and base in water or another solvent, homogenizing the suspension, filtering the suspension, and then drying the suspension. Claim 7. The complex is obtained by simultaneous salt formation and complexation. Claim 1. Column 2, lines 12-15; claim 1, column 8, lines 41-42.

Applicant's invention concerns a method of determining a useful salt of both acidic and basic drugs. See pending application page 3, lines 6-8 and lines 30-33. The salt of the drug is made before the drug as the salt is added to cyclodextrin to form the complex. See pending application, at least page 8, line 24 spanning to page 9, line 23. See also, the example provided for illustration purposes on page 11, lines 11-12.

Second, contrary to the statement that Tables 1, 2 and 4 of Cheisi, '029 allow for a comparison of the solubility properties of a series of salts (11/20/2003 Office Action, page 5), said tables do not describe in any detail a method to determine a useful salt among a series of salts as discussed and claimed in Applicant's pending application. There are insufficient controls in Cheisi, '029 to teach or to allow anyone to appreciate and practice Applicant's invention without the benefit of Applicant's disclosure. In Tables 1, 3, and 4 of Cheisi, '029, the same salt is used to form the complex of the acidic drug, base, and cyclodextrin. Although, Table 2 shows two different salts being used, the instant solubility is

identical between the two salts used with the same cyclodextrin and acidic drug. See column 5, lines 46-47. Applicant's invention concerns determining a useful salt from within a series of salts to use when forming a cyclodextrin complex. See Figure I and text on page 7, line 20. There is nothing explicit or inherent in Cheisi, '029 to make one of ordinary skill in the art look at a series of salts to determine which salt would be the "useful" salt within a series.

Cheisi, '029 merely provides high solubility multicomponent inclusion complexes consisting of an acidic drug, a cyclodextrin and a base. The requirements discussed and claimed in Cheisi, '029 prevent the reference from anticipating Applicant's invention for the reasons stated herein and in previous responses to ongoing rejections under 102(a). Therefore, Applicant respectfully requests that this rejection be reconsidered and withdrawn.

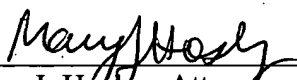
Correction of PAIR

Applicant requests that PAIR be corrected to provide that the Office Action mailed 06/15/2005 is a non-final office action. In PAIR, it is stated as being final.

Conclusion

Applicants believe that the claims are in order for allowance, early notice of which is requested. If Examiner has any questions concerning this application, Examiner is invited to contact the below-signed attorney.

Respectfully submitted,



Mary J. Hosley, Attorney
Registration No. 48,324

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Pfizer, Inc
150 East 42nd Street, Floor 5
New York, NY 10017-5612
Telephone No. 212.733-0460
Telefax No. 212.573-1939